Re-evaluation Decision RVD2011-05

Clopyralid

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Re-evaluation Decision for Clopyralid

After a thorough re-evaluation of the herbicide clopyralid, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is granting continued registration of products containing clopyralid for sale and use in Canada.

An evaluation of available scientific information found that products containing clopyralid have value in the food and crop industry and do not present unacceptable risks to human health or the environment. As a condition of the continued registration of clopyralid uses, new risk-reduction measures must be included on the labels of all clopyralid product, and additional data are required under section 12 of the *Pest Control Products Act*.

The regulatory approach regarding the re-evaluation of clopyralid was first proposed in the Proposed Re-evaluation Decision PRVD2010-17, *Clopyralid*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of the PMRA's regulatory process for the re-evaluation of clopyralid and also summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2010-17. To comply with this decision, registrants of clopyralid products will be informed of the specific requirements affecting their product registration(s).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration.[3] The Act also requires that products have value[4] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticide and Pest Management portion of Health Canada's website at www.healthcanada.gc.ca/pmra.

What is Clopyralid?

Clopyralid is a selective systemic broadleaf weed herbicide. It is registered for postemergence use on terrestrial food crops, terrestrial feed crops, industrial oilseed and fibre crops, forest and woodlands, ornamental outdoors, and industrial and domestic vegetation control for non-food sites. Clopyralid may be used alone to control broadleaf weeds or in co-formulation with MCPA or flumetsulam to control both broadleaf and grassy weeds. It is applied once or twice per year at a rate of 75 to 298.8 g a.i./ha by ground equipment only.

Health Considerations

Can Approved Uses of Clopyralid Affect Human Health?

Clopyralid is unlikely to affect your health when used according to the label directions.

Potential exposure to clopyralid may occur through diet (food and water), when applying the product or by entering treated sites. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when using clopyralid products according to the label directions.

Clopyralid is of low toxicity by the oral, inhalation and dermal route in laboratory animals. It is severely irritating to the eyes, non-irritating to skin and non-sensitising. Clopyralid did not cause cancer in animals and was not genotoxic. There was also no indication that clopyralid caused damage to the nervous system and there were no effects on reproduction. The first signs of toxicity in animals given daily doses of clopyralid over longer periods of time were effects on body weight, the stomach and the liver. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

When clopyralid was given to pregnant animals, effects on the developing fetus were observed at doses that were toxic to the mother. In particular, an increase in hydrocephaly in rabbit fetuses occurred at a maternally toxic dose. Consequently, extra protective measures were applied during the risk assessment to further reduce the allowable level of human exposure to clopyralid.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Human exposure to clopyralid was estimated from residues in treated crops and drinking water, including the most highly exposed subpopulation (for example, infants and children 1 to 2 years old). This aggregate exposure (i.e. to clopyralid from food and drinking water) represents less than 6% of the acute reference dose and less than 13% of the chronic reference dose.

The *Food and Drugs Act* prohibits the sale of adulterated food, namely, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

MRLs for clopyralid are currently specified for barley, blueberries, broccoli, cabbages, cauliflower, Chinese broccoli, Chinese mustard cabbages, kohlrabi, napa Chinese cabbages, oats, strawberries, wheat, cattle, goats, hogs, horses, poultry, sheep, eggs and milk or processed foods derived from these foods. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL will be implemented in the future, as indicated in the December 2009 Information Note, *Progress on Minimizing Reliance on the 0.1 Parts per Million as a General Maximum Residue Limit for Food Pesticide Residue*.

Non-Occupational Risks From Clopyralid

Clopyralid is not registered for use in residential areas, thus a residential risk assessment was not required.

Aggregate risk from exposure incurred as a patron of a "Pick Your Own" facility is not of concern.

Dermal exposure to clopyralid residues during a pick-your-own operation was considered to be negligible and not of concern, thus an aggregate dermal and oral pick your own risk assessment was not required.

Occupational Risks From Handling Clopyralid

Occupational risks are not of concern.

Risk estimates associated with mixing, loading and applying activities are not of concern and additional personal protective equipment (PPE) are not required beyond what is currently specified on the label.

Postapplication risks are not of concern.

Risks to workers entering crops treated with clopyralid are not of concern. The minimum 12 hour restricted-entry interval (REI) is required for all uses.

Environmental Considerations

What Happens When Clopyralid Is Introduced Into the Environment?

Clopyralid poses a potential risk to non-target terrestrial plants, therefore, additional risk reduction measures need to be observed.

When clopyralid is released into the environment some of it can be found in soil and surface water. Clopyralid in soil or water is not susceptible to hydrolysis or phototransformation. However, it breaks down through microbial transformation with carbon dioxide being the only major transformation product. Clopyralid is non persistent to persistent in soil and water.

Clopyralid is very soluble in water and does not adsorb strongly to soils and therefore may leach into groundwater and enter surface water in run-off. Water monitoring has revealed clopyralid residues in groundwater as well as surface water. Clopyralid is not expected in the air because of its low volatility and has low potential for bioconcentration in biota.

Clopyralid, when used according to label directions, does not present a risk to earthworms, bees, beneficial arthropods and other insects, small mammals, birds, and aquatic organisms. However, clopyralid may pose a risk to some non-target terrestrial plants. In order to minimize the potential exposure to plants, spray buffer zones are required. The width of these spray buffer zones must be specified on the product label.

Value Considerations

What is the Value of Clopyralid?

Clopyralid contributes to weed management in a variety of crop and non-crop sites when used in accordance with the label directions.

Unlike other auxin-mimics, clopyralid can be applied to many broadleaf crops. It controls many troublesome perennial broadleaf weeds including Canada thistle, dandelion and perennial sowthistle. It can be co-formulated or tank mixed with many other herbicides to broaden weed control spectrum. Clopyralid is the only postemergence broadleaf herbicide registered for use in Canada on cole crops (cabbage, cauliflower, broccoli, Brussels sprouts, rutabaga, Chinese cabbage, radish, kohlrabi and mustard cabbage). Furthermore, it is the only alternative postemergence broadleaf herbicide to bentazon in highbush blueberries, and to 2,4-D in cranberries and strawberries (harvest year, renovation). Other non-selective postemergence herbicides are registered for use on shelterbelts, however, clopyralid is the only selective postemergence herbicide registered for this use. When used in rotation with active ingredients from other herbicide groups, clopyralid plays a role in mitigating resistance development in weeds.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

Although no risk of concern were identified, measures in addition to those already identified on existing clopyralid products labels, are required to further protect human health and the environment. The following additional key risk-reduction measures are required (See also Appendix II).

Human Health

- A restricted-entry interval to protect workers entering treated sites
- Statements for personal protective equipment are updated and standardized between the product labels
- A statement clarifying that product is not to be used in greenhouses
- A statement to promote best management practices to minimize human exposure from spray drift or spray residues resulting from drift

Environment

- Additional advisory label statements and specification of buffer zones to protect non-target terrestrial plants
- Advisory label statements to indicate that the use of clopyralid may result in contamination of groundwater and surface water through leaching and runoff, respectively

What Additional Scientific Information is Being Requested?

Recent analytical data to confirm current levels of impurities of human health and environment concern in technical grade clopyralid products are required under section 12 of the *Pest Control Products Act*. The registrant of this active ingredient must provide these data (See Appendix I) or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter.

Other Information

The relevant test data on which the decision is based are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this decision on clopyralid within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*

Appendix I Data Requirements for Clopyralid

The following data are required under section 12 of the *Pest Control Product Act*.

DACO 2.13.4 Impurities of Human Health or Environmental Concern

The registrant must provide analytical data from at least five recent batches of technical grade products for hexachlorobenzene, pentachlorobenzene and tetrachlorobenzenes (three isomers) from a GLP-compliant or government-accredited laboratory. The analytical method(s) used must utilize the lowest practical limits of quantitation and be fully specified, either by reference to a standard method or by inclusion of a detailed description together with validation data.

Appendix II Label Amendments for Products Containing Clopyralid

The label amendments presented below do not include all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

Technical Class Products:

I) The following warning statement must be included on the **PRIMARY DISPLAY PANEL**:

Danger: Eye Irritant

II) The following precautionary statement must be included on the **SECONDARY DISPLAY PANEL**:

Severely irritating to eyes. DO NOT get in eyes.

Commercial Class Products:

I) The following statements must be included in a section entitled **PRECAUTIONS**:

Workers must wear long pants, a long-sleeved shirt and chemical-resistant gloves. Goggles or a face shield are required during mixing and loading. Gloves are not required to be worn during groundboom applications but are required for mixing/loading, clean-up and repair.

Do not enter or allow workers entry into treated areas for 12 hours following application to all crops.

II) The following statements must be included in a section entitled **DIRECTIONS FOR USE**:

Do not use in greenhouses.

Apply only when the potential for drift to areas of human habitation or areas of human activity (such as houses, cottages, schools and recreational areas) is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air.

Buffer Zones:

Uses of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer, and spot treatment.

For application to rights-of-way, buffer zones for protection of sensitive terrestrial habitats are not required; however, the best available application strategies which minimize off-site drift, including meteorological conditions (for example, wind direction, low wind speed) and spray equipment (for example, coarse droplet sizes, minimizing height above canopy), should be used.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, woodlots, hedgerows, riparian areas and shrublands).

Method of application	Crop	Buffer Zones (metres) Required for the Protection of Terrestrial habitat
Field sprayer*	Wheat, barley, oats, flax, canola, forage grasses, high-bush blueberry, low-bush blueberry, strawberry, sugar beet, rutabaga, cabbage, broccoli, cauliflower, field corn (hybrid), canary seed, balsam fir, Christmas tree plantations, shelterbelts, poplar and their hybrids, non-crop uses, rangeland and grass pasture	2**
	Apple	3

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

** Buffer zones for the protection of terrestrial habitats are not required for use on rights-of-way, including railroad ballast, rail and hydro rights-of-way, utility easements, roads, and training grounds and firing ranges on military bases.

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

III) The following statements must be included in a section entitled **ENVIRONMENTAL HAZARDS**:

TOXIC to non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.

The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (for example, sandy soil) and/or the depth to the water table is shallow.

To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to: heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (for example, soils that are compacted or fine textured such as clay).

Avoid application of this product when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.